



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/051,290	08/31/98	MOREAU DEFARGES	A 1029/168

QM31/0218

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EXAMINER	
THANH, L	
ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 02/18/99

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
09/051,290

Applicant(s)

Moreau Defarges et al.

Examiner

LoAn Thanh

Group Art Unit

3734



☒ Responsive to communication(s) filed on Aug 31, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-12 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Aug 31, 1998 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Drawings

1. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Reference numeral 17a and 8a. Correction is required. ✓
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference numeral 55 \Rightarrow 3? which is directed to a cap. Correction is required.
4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cap must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. ✓
5. The drawings are objected to because in the figures 1 and 2 is the armed and trigger position. In figure 1, there is a ring but no knurled wheel and in figure 2 there is a knurled wheel but no ring. Further, the percussion device has no designated reference numeral and is not in the figures. Further, ^{process} orifice 61 does not look like an orifice but rather some form of a cap. ✓
Correction is required.

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6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "14" and "20" have both been used to designate peripheral envelope and plurality of tabs. Correction is required. ²⁰

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because of the following:

Reference character "41" has been used to designate both raised zones and elastic member. ^{raised zones} ✓

Reference character "31" has been used to designate both outlet orifice and active principle. Correction is required. ⁽²⁹⁾ ✓

Specification

8. The disclosure is objected to because of the following informalities:

Through out the specification two articles are directed to an object. For example, the first occurrence of such is on page 2a, line 23. "[t]he said device" should be "the device".

It is unclear what applicant meant by "the latter" on page 4, line 7.

On page 4, line 32, it is unclear whether the ring (25) should be the knurled wheel (46). The figure 1 and 2 is the armed and trigger position. In figure 1, there is a ting but no knurled wheel and in figure 2 there is a knurled wheel but no ring.

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It is unclear whether applicant intended "latter" on page 4, line 39 to be "former" since the latter would be the hinge 48 and the former would be the safety device 47. It would be even more clear if Applicant just recited "the safety device" in place of "the latter" to avoid confusion.

Reference numeral 4, 5 have been designated as "ends" and "front surfaces".

It is unclear what Applicant intended with "the latter" on page 10, line 18 since it is not clear whether Applicant meant the cartridge or the cavity.

Appropriate correction is required.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.


The following is a quotation of 37 CFR 1.71(a)-(c):

- (a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.
- (b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.
- (c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because it fails to adequately teach how to make and/or use the invention, i.e, failing to provide an enabling disclosure. It is unclear

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whether Applicant has the reverse intentions for the safety device on page 5 lines 7-14. Is the locked safety device when the percussion device cannot be armed and when it is unlocked the percussion device is in the trigger position? It is unclear how the safety device can function safely if it is unlocked that it cannot arm the percussion and when it is locked it can arm the percussion device. It is further unclear what elements comprises the percussion device. Is it only the striker and the rod?

A large handwritten curly bracket on the right side of the text, spanning from the first sentence to the last sentence of the paragraph, with a question mark next to it.

Claim Objections

10. Claims 1- 12 are objected to because of the following informalities:

In Claim 1, line 15, it is recommended that Applicant delete the second occurrence of "the" to avoid two articles for one object.

In line 18, it is recommended to delete the first occurrence of "the".

Claim 4, line 7, "the other" seems to be grammatically incorrect or incomplete.

In claim 5, line 3, delete the second occurrence of "the".

In claim 6, line 6, delete the first occurrence of "the".

In claim 8, line 3, delete the second occurrence of the "the".

Line 4, delete the first occurrence of "the".

Line 7, delete the first occurrence of "the".

The claims contain reference numeral directed to elements which are unnecessary since the claim is not read in light of the reference numeral. Further, it appears that some of the reference

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numeral are incorrectly directed to the elements in the claim. It is suggested that Applicant deletes all the reference numeral designations in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear if Applicant is attempting to set up the claim as in a Jepson claim to indicate what is prior art and the improvement thereof. If this is so, it is vague and unclear what the admitted prior art is and where the structural improvement begins. See MEP. 2129. Further, "the body" in lines 4 and 5 lack antecedent basis.

Claim 3 is vague and indefinite because it is unclear what "if appropriate" is intended. It is ambiguous whether Applicant is claiming the tinted plastic material or not.

Claim 4 is vague and indefinite because it is unclear whether the rod is the percussion member or part of the percussion member. Further, since the diameter of the rod and the percussion member is not positively claimed it lacks proper antecedent basis in line 6.

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Claim 5 is vague and indefinite because it is unclear what "at one of its ends" is intended and what structure this encompasses. It is further unclear if there are more than one end then which end is Applicant referring to. In line 3, "the engagement" lacks antecedent basis. It is suggested Applicant deletes the first occurrence of "the" in line 3.

Claim 8 is vague and indefinite because it is unclear what "at their ends" is intended. It is further unclear what "ends" Applicant is referring to since it could be the end of the cartridge or the ends of the lateral walls.

Claim 9 recites the limitation "the studs" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Colavecchio (U.S. Patent No. 5,256,142).

See figures 1-3. Colavecchio discloses a needleless injection device having a cartridge made up of a first element made of glass (16) to contain the medicament and a second element made of

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plastic (10) which surrounds the glass container (16). Colavecchio shows a first element (16) of general cylindrical shape with an orifice at each end of the cartridge.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becton Dickinson and Company (BD and Co.) (GB 677,523) in view of Colavecchio (U.S. Patent No. 5,256,142).

See figures 6-7 and 13. BD and Co. discloses needless injection device having a cartridge (31) that is surrounded by body (20) both elements made of any suitable materials, a cap at the distal end attached to the nose of the injection device with a seal (47") made of suitable material such rubber or plastic. See page 2, line 129 to page 3, line 8. The rod (22) considered to be the plunger is pushed to move the stopper (32) through the cartridge (31) in order to dispense the medication out the other orifice (46). However, BD and Co. does not disclose the materials of glass and plastic of the first and second element respectively, but does teach any suitable materials to construct. Colavecchio teaches "the same field of endeavor". Colavecchio teaches suitable materials of the first element and second element to be glass and plastic respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the materials specified by Colavecchio as for the

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suitable materials of the first element and second elements of BD and Co. Further it would have been an obvious design choice as to the materials used to construct the first and second elements since it is well known to use glass and plastic materials in medical devices such as needleless injection devices.

16. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colavecchio (U.S. Patent No. 5,256,142) in view of Stiehl et al. (U.S. Patent No. 5,350,367).

Colavecchio teaches all the limitations of the claims except a plurality of plastic material gaps in the plastic overmould of the cartridge to produce slots for improving visibility of the first element. Stiehl et al. teaches analogous art of a dispensing hypodermic syringe. Stiehl et al. teaches a first element of which is the glass ampoule which is inserted into a plastic holder through the open side wall. Stiehl et al. further discloses a viewing window (26) and it would be also inherent that through the open side wall the user can also view the contents of the glass ampoule. It would have been obvious to one of ordinary skill in the art at the time the invention was made to put a plurality of windows in the plastic second element of Colavecchio as taught by Stiehl in order to provide visibility of the medicament contained in the glass ampoule.

Allowable Subject Matter

17. Claims 8-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Claims 8-11 would be allowable since the prior art of record fails to teach a cap which encloses the distal end of the cartridge having lateral walls with raised zones which clip into impressions provided on the outer lateral walls of the cartridge.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703) 308-1344. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

LoAn H. Thanh

Patent Examiner

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Date: February 11, 1999



WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER